

Notice of Allowability

Application No.

09/890,379

Examiner

Mary E. Mosher, Ph.D.

Applicant(s)

HEENEY, JONATHAN LUKE

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/17/2003.
2. ☒ The allowed claim(s) is/are 46-56.
3. ☒ The drawings filed on 09 January 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input checked="" type="checkbox"/> Other <i>Post-allowance notice</i> . |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lauren Emr on 1/21/2004.

The application has been amended as follows:

The claims have been amended as shown on the attached sheet. The claims have been amended (1) to move a key limitation (avoiding repeated exposure of vector proteins) from the preamble to the body of independent claim 46; (2) to clarify that the administered composition induces an immune response that is not limited to a protective immune response, by replacing "vaccine composition" with "immunogenic composition"; and (3) to clarify the antecedent for "said vector" in claims 54 and 55

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is now 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027 until approximately 1/26/2004, 571-272-0902 thereafter. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

1/21/04


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 1600

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Claims:

46. (Amended) A method for inducing or stimulating a T-helper cell response in a human or animal against at least one antigen, ~~while avoiding repeated exposure of vector proteins or vector encoded proteins, the method comprises~~ comprising the steps of:

- i. administering a first vaccine immunogenic composition comprising a first vector encoding said antigen;
- ii. administering a second vaccine immunogenic composition comprising a second vector encoding said antigen and;
- iii. administering a third vaccine immunogenic composition comprising a third vector encoding said antigen;

wherein the first, second and third vectors are not the same and are chosen to avoid repeated exposure of vector proteins or vector encoded proteins;

wherein the first, second and third vaccine immunogenic compositions are administered sequentially to the animal or human;

wherein at least part of said vectors functions as an adjuvant;. and

wherein the antigen is an antigen of a lentivirus.

47. The method according to claim 46, wherein the lentivirus causes a temporary or long lasting immune impairment.

48. The method according to claim 48, wherein said adjuvant function directs the immune response toward a more T helper 1 type or a more T helper 2 type of response or both.

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49. The method according to claim 46, wherein said antigen comprises at least an immunogenic part, derivative and/or analogue of a lentivirus *gag*, *pol*, *rev*, *tat*, *nef* or *env* protein or a combination thereof.

50. (Amended) The method according to claim 46, wherein at least one of said ~~vaccine~~-immunogenic compositions comprises a nucleic acid encoding at least one proteinaceous molecule capable of inducing and/or boosting an immune response against said antigen.

51. The method according to claim 50, wherein said proteinaceous molecule comprises said antigen, or an immunogenic part derivative or analogue thereof.

52. The method according to claim 50, wherein said nucleic acid comprises a nucleic acid selected from the group consisting of a Semliki Forest Virus, a poxvirus, a herpes virus and an adenovirus, or a combination thereof.

53. The method according to claim 50, wherein said proteinaceous molecule is selected from the group consisting of a co-stimulatory protein, an immune response inhibitory protein, an interleukin, a major histocompatibility complex protein and a functional part derivatives and/or analogues thereof.

54. (Amended) The method according to claim 46, wherein said first, second, and/or third vector comprises a nucleic acid which encodes at least one proteinaceous molecule capable of modulating an immune response.

55. (Amended) The method according to claim 46, wherein said first, second, and/or third vector is a nucleic acid delivery vehicle comprising said nucleic acid.

56. The method according to claim 55, wherein said nucleic acid delivery vehicle is selected from the group consisting of a Semliki Forest Virus particle, a pox virus particle, a herpes virus particle and an adenovirus particle.